



THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

CAI *et al.*

Appl. No.: 10/580,263

§ 371 Date: May 25, 2006

**For: Derivatives of Gambogic Acid and
Analogues as Activators of Caspases
and Inducers of Apoptosis**

Confirmation No.: 2574

Art Unit: 1626

Examiner: (to be assigned)

Atty. Docket: 1735.0940001/RWE/BAH

Information Disclosure Statement

Mail Stop Amendment

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

Listed on accompanying IDS Forms are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. Copies of documents FP1-FP2 and NPL1-NPL48 are submitted. However, in accordance with 37 C.F.R. § 1.98(a)(2), no copies of U.S. patents and patent application publications cited on the attached IDS Forms are submitted.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached IDS Forms based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed within three months of the date of entry of the national stage as set forth in 37 C.F.R. § 1.491 in an international application or before the mailing date of a first Office Action on the merits. No statement or fee is required.

Lu, G.B. *et al.*, *Yao Hsueh Hsueh Pao* 19:636-639 (1984), Document NPL27, is in a foreign language. The relevance of Document NPL27 may be ascertained from the English-language abstract appearing at page 639 of that reference.

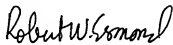
Qu, B.X. *et al.*, *Zhongguo Zhongliu Linchuang* 18:50-52 (1991), Document NPL33, is in a foreign language. The relevance of Document NPL33 may be ascertained from the English-language abstract appearing at page 52 of that reference and from the English-language abstract provided herewith as Document NPL15.

It is respectfully requested that the Examiner initial and return a copy of the enclosed IDS Forms, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)		Application Number	10/580,263
		\$ 371 Date	May 25, 2006
		First Named Inventor	Sui Xiong CAI
		Art Unit	1626
		Examiner Name	(to be assigned)
		Attorney Docket Number	1735.0940001/RWE/BAH
Sheet	1	of	1

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	US1	3,989,816	11-02-1976	Rajadhyaksha, V.J.	
	US2	4,444,762	04-24-1984	Rajadhyaksha, V.J.	
	US3	6,462,041 B1	10-08-2002	Cai <i>et al.</i>	
	US4	6,335,429 B1	01-01-2002	Cai <i>et al.</i>	
	US5	6,613,762 B2	09-02-2003	Cai <i>et al.</i>	
	US6	7,176,234 B2	02-13-2007	Cai <i>et al.</i>	
	US7				
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	FP1	WO 2000/044216 A2	08-03-2000	Cytovia, Inc.	
	FP2	WO 2004/002428 A2	01-08-2004	Cytovia, Inc.	
	FP3				
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NON PATENT LITERATURE DOCUMENTS

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	NPL1	Adawadkar, P.D. <i>et al.</i> , "Colouring Matters of <i>Garcinia morella</i> : Part VIII – Morellinol, Dihydromorelloflavone and Morelloflavone-7"- β -glucoside," <i>Indian J. Chem. 14B</i> :19-21, Council of Scientific & Industrial Research (1976)	
	NPL2	Adjei, A.A. <i>et al.</i> , "Synergy of the Protein Farnesyltransferase Inhibitor SCH66336 and Cisplatin in Human Cancer Cell Lines," <i>Clin. Cancer Res.</i> 7:1438-1445, American Association for Cancer Research, Inc. (2001)	
	NPL3	Ahmad, S.A. <i>et al.</i> , "Gamboge. Part II," <i>J. Chem. Soc. (C)</i> :772-779, The Chemical Society (1966)	
	NPL4	Almond, J.B. and Cohen, G.M., "The proteasome: a novel target for cancer chemotherapy," <i>Leukemia</i> 16:433-443, Nature Publishing Group (April 2002)	
	NPL5	Asano, J. <i>et al.</i> , "Cytotoxic Xanthones from <i>Garcinia hanburyi</i> ," <i>Phytochem.</i> 41:815-820, Elsevier Science Ltd. (1996)	
	NPL6	Batteux, F. <i>et al.</i> , "Gene Therapy of Experimental Autoimmune Thyroiditis by In Vivo Administration of Plasmid DNA Coding for Fas Ligand," <i>J. Immunol.</i> 162:603-608, The American Association of Immunologists (1999)	
	NPL7	Bhat, H.B. <i>et al.</i> , "The Colouring Matters of <i>Garcinia morella</i> : Part V– Isolation of Desoxymorellin & Dihydroisomorellin," <i>Indian J. Chem.</i> 2:405-410, The Council of Scientific & Industrial Research (1964)	
	NPL8	Blanke, C.D., "Celecoxib With Chemotherapy in Colorectal Cancer," <i>Oncology (Huntingt)</i> 16(No. 4 Suppl. 3):17-21 (April 2002)	
	NPL9	Borivant, M. <i>et al.</i> , "Lamina Propria T Cells in Crohn's Disease and Other Gastrointestinal Inflammation Show Defective CD2 Pathway-Induced Apoptosis," <i>Gastroenterology</i> 116:557-565, American Gastroenterological Association (1999)	
	NPL10	Cao, S.-G. <i>et al.</i> , "Novel Cytotoxic Polyprenylated Xanthonoids from <i>Garcinia gaudichaudii</i> (Guttiferae)," <i>Tetrahedron</i> 54:10915-10924, Elsevier Science Ltd. (1998)	

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<i>Attorney Docket Number</i>	1735.0940001/RWE/BAH				
Sheet	2	of	5		

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published	T ²
	NPL11	Cao, S.-G. <i>et al.</i> , "Cytotoxic Caged Tetraprenylated Xanthonoids from <i>Garcinia gaudichaudii</i> (Guttiferae)," <i>Tetrahedron Lett.</i> 39:3353-3356, Elsevier Science Ltd. (1998)	
	NPL12	Chinnaiyan, A.M. <i>et al.</i> , "The inhibition of pro-apoptotic ICE-like proteases enhances HIV replication," <i>Nat. Med.</i> 3:333-337, Nature Publishing Company (1997)	
	NPL13	Coven, T.R. <i>et al.</i> , "PUVA-induced lymphocyte apoptosis: Mechanism of action in psoriasis," <i>Photodermatol. Photoimmunol. Photomed.</i> 15:22-27, Blackwell Munksgaard (1999)	
	NPL14	Crawford, K.W. and Bowen, W.D., "Sigma-2 Receptor Agonists Activate a Novel Apoptotic Pathway and Potentiate Antineoplastic Drugs in Breast Tumor Cell Lines," <i>Can. Res.</i> 62:313-322, American Association for Cancer Research, Inc. (January 2002)	
	NPL15	Database Biosis, Accession No. PREV199191109495, Qu, B.-X. <i>et al.</i> , "The Experimental Studies on Antineoplastic Action of Gambogic II," one page (1991)	
	NPL16	Giermasz, A. <i>et al.</i> , "Potentiating Antitumor Effects of a Combination Therapy with Lovastatin and Butyrate in the Lewis Lung Carcinoma Model in Mice," <i>Int. J. Cancer</i> 97:746-750, Wiley-Liss, Inc. (February 2002)	
	NPL17	Heenen, M. <i>et al.</i> , "Methotrexate induces apoptotic cell death in human keratinocytes," <i>Arch. Dermatol. Res.</i> 290:240-245, Springer-Verlag (1998)	
	NPL18	Infante, A.J. <i>et al.</i> , "The clinical spectrum in a large kindred with autoimmune lymphoproliferative syndrome caused by a Fas mutation that impairs lymphocyte apoptosis," <i>J. Pediatr.</i> 133:629-633, Mosby, Inc. (1998)	
	NPL19	Kalemkerian, G.P. and Ou, X., "Activity of fenretinide plus chemotherapeutic agents in small-cell lung cancer cell lines," <i>Cancer Chemother. Pharmacol.</i> 43:145-150, Springer-Verlag (1999)	
	NPL20	Karanjgaonkar, C.G. <i>et al.</i> , "Morellic, Isomorellic and Gambogic Acids," <i>Tetrahedron Letts.</i> 7:687-691, Pergamon Press Ltd. (1966)	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				<i>Application Number</i>	10/580,263
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				<i>Examiner Name</i>	(to be assigned)
<i>Sheet</i>	3	of	5	<i>Attorney Docket Number</i>	1735.0940001/RWE/BAH

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published	T ²
	NPL21	Kelland, L.R. <i>et al.</i> , "Preclinical Antitumor Activity and Pharmacodynamic Studies with the Farnesyl Protein Transferase Inhibitor R115777 in Human Breast Cancer," <i>Clin. Cancer Res.</i> 7:3544-3550, American Association for Cancer Research, Inc. (2001)	
	NPL22	Kyprianou, N. and Benning, C.M., "Suppression of Human Prostate Cancer Cell Growth By α 1-Adrenoceptor Antagonists Doxazosin and Terazosin via Induction of Apoptosis," <i>Cancer Res.</i> 60:4550-4555, American Association for Cancer Research, Inc. (2000)	
	NPL23	Leong, Y.-W. <i>et al.</i> , "Forbesione, a Modified Xanthone from <i>Garcinia forbesii</i> ," <i>J. Chem. Res. (S)</i> :392-393, The Royal Society of Chemistry (1996)	
	NPL24	Lin, L.-J. <i>et al.</i> , "Isogambogic Acid and Isomorellinol from <i>Garcinia Hanburyi</i> ," <i>Magn. Reson. Chem.</i> 31:340-347, John Wiley & Sons, Ltd. (1993)	
	NPL25	Liu, W.M. <i>et al.</i> , "The <i>in vitro</i> activity of the tyrosine kinase inhibitor ST1571 in BCR-ABL positive chronic myeloid leukaemia cells: synergistic interactions with anti-leukaemic agents," <i>Br. J. Cancer</i> 86:1472-1478, Nature Publishing Group (May 2002)	
	NPL26	López-Hoyos, M. <i>et al.</i> , "Regulation of B cell apoptosis by Bcl-2 and Bcl-X _L and its role in the development of autoimmune diseases (Review)," <i>Int. J. Mol. Med.</i> 1:475-483, D. A. Spandidos (1998)	
	NPL27	Lu, G.B. <i>et al.</i> , "Isolation and Structure of Neo-gambogic Acid from Gamboge (<i>Garcinia hanburyi</i>)," <i>Yao Hsueh Hsueh Pao</i> 19:636-639, The Chinese Pharmaceutical Association and The Institute of Materia Medica (1984)	
	NPL28	Motwani, M. <i>et al.</i> , "Augmentation of Apoptosis and Tumor Regression by Flavopiridol in the Presence of CPT-11 in Hct116 Colon Cancer Monolayers and Xenografts," <i>Clin. Cancer Res.</i> 7:4209-4219, American Association for Cancer Research, Inc. (2001)	
	NPL29	Ohsako, S. and Elkon, K.B., "Apoptosis in the effector phase of autoimmune diabetes, multiple sclerosis and thyroiditis," <i>Cell Death Differ.</i> 6:13-21, Nature Publishing Group (1999)	
	NPL30	Ollis, W.D. <i>et al.</i> , "The Constitution of Gambogic Acid," <i>Tetrahedron</i> 21:1453-1470, Pergamon Press Ltd. (1965)	

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	NPL31	O'Reilly, L.A. & Strasser, A., "Review: Apoptosis and autoimmune disease," <i>Inflamm. Res.</i> 48:5-21, Birkhäuser Verlag, Basel (1999)	
	NPL32	Ozawa, M. <i>et al.</i> , "312-nanometer Ultraviolet B Light (Narrow-Band UVB) Induces Apoptosis of T Cells within Psoriatic Lesions," <i>J. Exp. Med.</i> 189:711-718, The Rockefeller University Press (1999)	
	NPL33	Qu, B.-X. <i>et al.</i> , "The Experimental Studies on Antineoplastic Action of Gambogic II," <i>Zhongguo Zhongliu Linchuang</i> 18:50-52, Tianjin: Tianjin-shi Yixue Zazhi She (1991)	
	NPL34	Rao, G.S.R. <i>et al.</i> , "Structure of moreollin, a pigment isolated from <i>Garcinia morella</i> Dessier," <i>Proc. Indian Acad. Sci.</i> 87A:75-86, The Indian Academy of Sciences (1978)	
	NPL35	Regar, E. <i>et al.</i> , "Stent development and local drug delivery," <i>Br. Med. Bull.</i> 59:227-248, Oxford University Press (2001)	
	NPL36	Rukachaisirikul, V. <i>et al.</i> , "Caged-Tetraprenylated Xanthenes from <i>Garcinia scortechinii</i> ," <i>Tetrahedron</i> 56:8539-8543, Elsevier Science Ltd. (2000)	
	NPL37	Savill, J., "Apoptosis in resolution of inflammation," <i>J. Leukoc. Biol.</i> 61:375-380, Society for Leukocyte Biology (1997)	
	NPL38	Sgadari, C. <i>et al.</i> , "HIV protease inhibitors are potent anti-angiogenic molecules and promote regression of Kaposi sarcoma," <i>Nat. Med.</i> 8:225-232, Nature America Inc. (March 2002)	
	NPL39	Tai, D.-I. <i>et al.</i> , "Activation of Nuclear Factor κ B in Hepatitis C Virus Infection: Implications for Pathogenesis and Hepatocarcinogenesis," <i>Hepatology</i> 31:656-664, W.B. Saunders Company (2000)	
	NPL40	Thoisson, O. <i>et al.</i> , "Cytotoxic Prenylxanthenes from <i>Garcinia bracteata</i> ," <i>J. Nat. Prod.</i> 63:441-446, American Chemical Society (2000)	

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Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published	T ²
	NPL41	Vaishnaw, A.K. <i>et al.</i> , "The molecular basis for apoptotic defects in patients with CD95 (Fas/Apo-1) mutations," <i>J. Clin. Invest.</i> 103:355-363, The American Society for Clinical Investigation Inc. (1999)	
	NPL42	Vilner, B.J. <i>et al.</i> , "Sigma-1 and Sigma-2 Receptors Are Expressed in a Wide Variety of Human and Rodent Tumor Cell Lines," <i>Cancer Res.</i> 55:408-413, American Association for Cancer Research, Inc. (1995)	
	NPL43	Wakisaka, S. <i>et al.</i> , "Modulation by proinflammatory cytokines of Fas/Fas ligand-mediated apoptotic cell death of synovial cells in patients with rheumatoid arthritis (RA)," <i>Clin. Exp. Immunol.</i> 114:119-128, Blackwell Science Ltd. (1998)	
	NPL44	Wu, J. <i>et al.</i> , "A highly rearranged tetraprenylxanthanoid from <i>Garcinia gaudichaudii</i> (Guttiferae)," <i>Tetrahedron Lett.</i> 42:727-729, Elsevier Science Ltd. (2001)	
	NPL45	Wu, X. <i>et al.</i> , "Mitochondrial Destabilisation and Caspase-3 Activation are Involved in the Apoptosis of Jurkat Cells Induced by Gaudichaudione A, a Cytotoxic Xanthone," <i>Planta Med.</i> 68:198-203, Georg Thieme Verlag Stuttgart (March 2002)	
	NPL46	Xu, Y.J. <i>et al.</i> , "Novel Cytotoxic, Polyprenylated Heptacyclic Xanthonoids from Indonesian <i>Garcinia gaudichaudii</i> (Guttiferae)," <i>Organic Lett.</i> 2:3945-3948, American Chemical Society (2000)	
	NPL47	Zhou, T. <i>et al.</i> , "Bisindolylmaleimide VIII facilitates Fas-mediated apoptosis and inhibits cell-mediated autoimmune diseases," <i>Nat. Med.</i> 5:42-48, Nature America Inc. (1999)	
	NPL48	Zou, C. <i>et al.</i> , "Combined effect of chemopreventive agent N-(4-hydroxyphenyl) retinamide (4-HPR) and γ -radiation on bladder cancer cell lines," <i>Int. J. Oncol.</i> 13:1037-1041, D. A. Spandidos (1998)	
	NPL49		
	NPL50		

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